GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2025
ANSWERED ON:21.07.2004
SALE OF ANTI-CANCER DRUGS
Paswan Shri Sukdeo

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government is aware that Mumbai based Sun Pharmaceuticals is selling anti-cancer drugs to cure infertility of women without the approval of DCGI (Drug Controller General of India);

(b) if so, the details thereof;

(c) whether the said drugs are affecting the health of the women rather than curing the infertility problems; and

(d) if so, the action taken/proposed to be taken in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (d): Yes Sir, In a News item appearing in Hindustan Times, New Delhi dated 24-9-2003, it was alleged that Letrozole, an oral anticancer drug is being marketed in the country for treatment of infertility. Letrozole had been approved for M/s Sun Pharmaceuticals on 28th June 2001, and to few other firms, as second line treatment of advanced Breast Cancer in women. Since, no formal approval was issued for its use as a fertility drug, the firm was issued a notice on 25-9-2003, to explain their alleged promotion of Lertozole as a fertility drug.

The firm explained that they did not make any, specific claim about its use in fertility on the label of their product. However, based on the articles published in international Medical Journals about beneficial use of letrozole in fertility enhancement, the gynecologists in the country have used it for their patients. The firm was however, `Warned` not to engage in any promotional activity, which leads to off-label use of anti-cancer drug letrozole for fertility enhancement. An advisory that Letrozole has not been approved as treatment for infertility has been issued to states.

Letrozole, which was developed as inhibitor of estrogen synthesis is reported to have been used by some Gynecologists in developed countries for treatment of infertility, and such studies have been published. Reports about the drug affects on the health of women have not come to notice.